

nPEP Plan of Action Toolkit

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FLORIDA DEPARTMENT OF HEALTH

*Non-Occupational
Post-Exposure
Prophylaxis (nPEP)
Resource Materials
for Health Care
Providers*



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INTRODUCTION

FOREWORD

This document contains key elements regarding Non-Occupational Post-Exposure Prophylaxis (nPEP) use. Frequent changes in standards of HIV prevention and care require that the guidelines be carefully reviewed by the medical team in your facility to assure that they conform to acceptable local and current approaches. Medical prevention and treatment updates are posted frequently to several websites, including the websites at <http://www.aidsinfo.nih.gov/> and www.cdc.gov/. It is recommended that every provider be familiar with all relevant guidelines.

*This document is not intended to replace clinical research literature or current United States Public Health Service (USPHS) Guidelines, and may not include the full range of prevention and treatment options for all patients. If there are questions regarding the provision of nPEP, it is recommended that a provider contact the **Clinician Consultation Center PEPLINE at 1-888-448-4911**.*

PEP DEFINITION

Post-exposure Prophylaxis (PEP) is the provision of medications to prevent transmission of a disease or illness following an occupational or non-occupational/perinatal exposure.

TWO TYPES OF PEP

Non-occupational PEP (nPEP) is taken when an individual is potentially exposed to HIV outside the workplace, for example, during episodes of unprotected sex or needle-sharing/injection drug use. Non-occupational exposure is any direct mucosal, percutaneous or intravenous contact with potentially infectious body fluids (not including perinatal situations).

Occupational PEP (oPEP) is taken when an individual working in a health care setting is potentially exposed to products or material(s) that could be or are known to be infected with HIV.

This document presents a plan of action to enable health care providers to address nPEP, the use of HIV medication to reduce the risk of HIV infection after a possible exposure to HIV. Patients presenting for nPEP should be evaluated as soon as possible so treatment, if indicated, can be initiated within recommended timeframes. To be most effective, evidence suggests a 72-hour timeframe for the initiation of nPEP following possible HIV exposure. nPEP initiation should be initiated as soon as possible following the exposure.

CHILDREN AND ADOLESCENTS

These guidelines do not specifically address the special needs of children and adolescents. Refer to New York State Department of Health AIDS Institute's guidance, *HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period*, <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-post-exposure-prophylaxis-for-children-beyond-the-perinatal-period/> or the American Academy of Pediatric's (AAP) guidance, *Postexposure Prophylaxis in Children and Adolescents for Nonoccupational Exposure to Human Immunodeficiency Virus* at <http://pediatrics.aappublications.org/content/111/6/1475>.

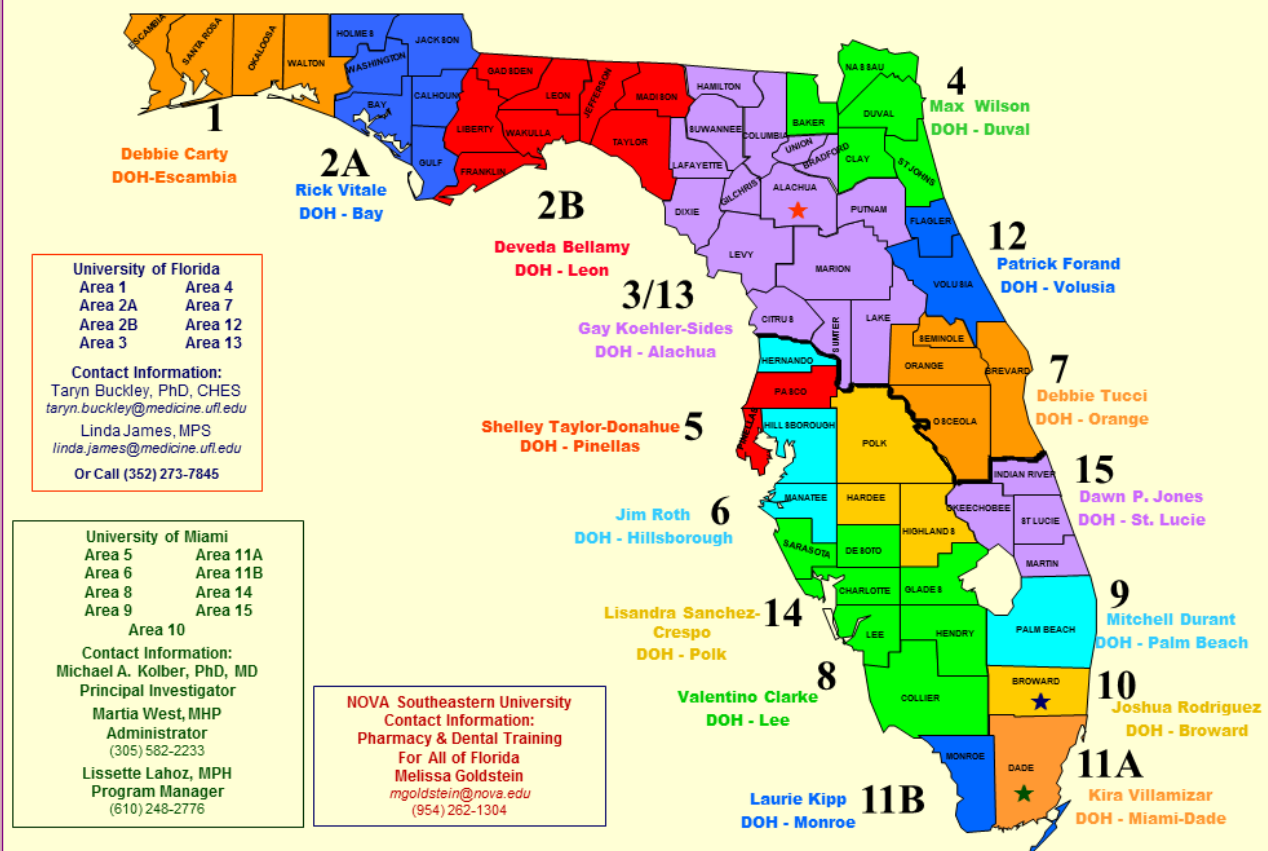
If you are a provider and have questions regarding the provision of nPEP, you can contact the **Clinician Consultation Center PEPLINE** at 1-888-448-4911 or the Southeast AIDS Education and Training Center (SE AETC) (see contact information and map below). Your area HIV/AIDS Program Coordinator (HAPC) can be a useful resource in locating services and resolving patient care issues that may arise in your region.

nPEP Quick Help Card - FLORIDA

For timely answers for urgent HIV exposure management call:

- The Clinician Consultation Center PEPLINE -
Phone Consultation
(888) 448-4911
9:00 a.m. – 2:00 a.m. (EST), seven (7) days a week
<http://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide/>

Florida HIV/AIDS Program Coordinators (HAPC) and Partners of the Southeast AIDS Education and Training Center (SE AETC)



October 12, 2015

For HIV/AIDS Program Coordinators contact information, please call Debbie Norberto at (850) 245-4444, ext. 2515, or email at Debbie.Norberto@flhealth.gov.

nPEP ACTION STEPS

1. **Evaluation**
2. **Risk Assessment**
3. **Treatment**
4. **Referral, Follow-up and Monitoring**

#1 – EVALUATION

Evaluation of the exposed patient should be conducted with the highest level of confidentiality. HIV reporting should take place as required by state laws.

CIRCUMSTANCES OF THE EXPOSURE AND nPEP MANAGEMENT

The following circumstances of the exposure and nPEP management should be recorded in the medical record with details, including:

- **EXPOSURE:** Date and time of exposure (is it within 72 hours?)
- **EXPOSURE TYPE:** Details of the exposure: type and amount of fluid or material and severity of exposure
- **INCIDENT:** Details of the incident: where and how exposure occurred, exposure sites on body
- **SOURCE:** Details about exposure source, if available:
 - HIV, hepatitis B and hepatitis C status
 - If the source is HIV infected, determine the stage of disease, HIV viral load, current and previous antiretroviral therapy and antiretroviral resistance information
- **PATIENT:** Details about the exposed patient:
 - Hepatitis A and hepatitis B vaccination and vaccine-response status
 - Other medical conditions, drug allergies and medications
 - Pregnancy and breast-feeding status

nPEP is not indicated for perceived exposures of negligible or no conceivable risk. Clinicians should be willing to decline requests for nPEP and provide supportive counseling and referrals in these situations.

#2 - RISK ASSESSMENT

The exposure should be evaluated for the potential to transmit HIV based on (1) the type of body substance involved, (2) the route and (3) HIV status of the source patient.

- Decisions should be individualized, weighing the likelihood of transmission against the potential benefits and risks of treatment.
- In sexual assault, the decision to initiate nPEP is based on whether a significant exposure has occurred rather than on the risk behavior of the alleged assailant.
- If the patient is too distraught to engage in a discussion about and/or commitment to the drug regimen at the initial assessment, the clinician should offer a first dose of the medication and make arrangements for a follow up within 24 hours to further discuss the indications for nPEP.

HIV STATUS ASSESSMENT

The likelihood of pre-existing HIV infection should be determined for all individuals presenting for nPEP. The following information should be obtained:

- Has the patient ever been tested, and if so, what was the date/result of their last HIV test?
- The number and types of unprotected exposures since the last HIV test. The likelihood of pre-existing HIV infection should be reviewed with the patient prior to nPEP prescription. If pre-existing HIV infection is likely, this information should be integrated into the risk-benefit assessment.

HIV TESTING OF SOURCE

If the source is available and consents, HIV testing should be completed using an HIV rapid test. If a rapid test is negative or nonreactive for the **SOURCE**, nPEP should be deferred unless there is a high

index of suspicion that the **SOURCE** may be in the seronegative window period of infection. The seronegative window is up to three months unless 4th generation or newer technology is used, which reduces the window to 15 days on average following the time of exposure. If using a confirmatory test as a backup, nPEP can be discontinued if the result is negative for the **SOURCE**.

Treatment of the patient is the PRIORITY and should NOT be delayed while waiting for lab results.

EVALUATE THE SOURCE ONLY IF KNOWN/AVAILABLE	
Known HIV infection	Unknown HIV infection
<ul style="list-style-type: none"> Obtain history of antiretroviral medication, recent viral load, CD4 cell count and date of results Consider evaluation and testing for other sexually transmitted infections, including hepatitis B and hepatitis C 	<ul style="list-style-type: none"> Obtain risk history and rapid HIV test (4th generation rapid or serum test preferred) Consider evaluation and testing for other sexually transmitted infections, including hepatitis B and hepatitis C <p><i>(modified from www.hivguidelines.org)</i></p>

The document, *Risk of HIV Transmission*, found at [http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/#APPENDIX B](http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/#APPENDIX_B): **PROBABILITY OF ACQUIRING HIV FROM A KNOWN HIV-INFECTED SOURCE**, outlines the probability of acquiring HIV from a known source as well as factors that may increase transmission risk. HIV transmission most frequently occurs during sexual or drug-use exposures; however, there are many factors that can influence transmission risk. The probability of transmission when the source person is in the acute and early stage of HIV infection (first six months) has been shown to be 8- to almost 12-fold higher than exposures that take place after the viral set point due to the presence of high HIV viral load levels.^{2,3} The presence of sexually transmitted infections (STIs) in either the source or exposed person also increases risk.⁴⁻⁶ Conversely, transmission risk has been shown to be significantly decreased in source persons who are receiving effective antiretroviral therapy (ART).⁷ The Centers for Disease Control and Prevention (CDC) is reviewing the most recent data and constructing mathematical models to update transmission risk.

Adapted from New York State Department of Health AIDS Institute's *UPDATE: HIV Prophylaxis Following Non-Occupational Exposure* (10-28-2014) at www.hivguidelines.org

SEXUAL ASSAULT OR INTRAVENOUS DRUG USERS (IDU)

All exposures sustained during sexual assault should be considered a risk for HIV. nPEP should be considered in all cases of sexual assault, especially in cases where the assailant is unknown. It is reasonable to offer nPEP to patients who have been sexually assaulted by men who are known to them, but whose sexual and injection drug use history is not known. Multiple other factors can be considered to determine the likelihood that the source of exposure is HIV infected. Local demographics should be taken into consideration when considering risk.

The NATIONAL SEXUAL ASSAULT TELEPHONE HOTLINE 1-800-656-HOPE (4673) offers Rape Crisis Center services to mitigate sexual assault trauma.

In Florida, call the Rape Crisis Hotline 1-888-956-7273.

For local service information in Florida, see the Florida Council Against Sexual Violence (FCASV) <https://www.fcasv.org/information/find-your-local-center> or their home website, <https://www.fcasv.org>.

#3 TREATMENT

<p>nPEP TREATMENT</p> <p>PREFERRED nPEP Regimen</p>	<div data-bbox="548 136 1349 510"> <p>RECOMMENDED REGIMEN FOR HIV nPEP</p> <p>TENOFOVIR 300 mg/*EMTRICITABINE 200 mg fixed dose combination (FDC) (TRUVADA®) PO daily</p> <p>PLUS</p> <p>RALTEGRAVIR (ISENTRESS®) 400 mg PO twice daily</p> <p>OR</p> <p>DOLUTEGRAVIR (TIVICAY®) 50 mg PO daily</p> <p><small>* Lamivudine 300 mg PO daily may be substituted for emtricitabine. A FDC is available when tenofovir is used with emtricitabine.</small></p> </div> <p>RENAL INSUFFICIENCY: The dosing of tenofovir and emtricitabine or lamivudine should be adjusted in patients with baseline creatinine clearance <50 mL/min. Tenofovir should be used with caution in exposed persons with renal insufficiency or who are taking concomitant nephrotoxic medications. Fixed-dose combinations should not be used in patients who need dose adjustment due to renal failure.</p>
<p>Duration of Therapy</p>	<p>28 Days (unless new information regarding source patient is available). Give a 3–5 day starter pack at initial visit (where available).</p>

ALTERNATIVE nPEP REGIMEN

<p>tenofovir 300 mg PO daily + *emtricitabine 200 mg, FDC (Truvada®) PO daily</p> <p>PLUS</p> <p>darunavir 800 mg PO daily OR atazanavir 300 mg PO daily OR fosamprenavir 1400 mg PO daily</p> <p>AND</p> <p>ritonavir 100 mg PO daily</p> <p><small>* Lamivudine 300 mg PO daily may be substituted for emtricitabine. A FDC is available when tenofovir is used with emtricitabine.</small></p>
<p>The dosing of tenofovir and emtricitabine or lamivudine should be adjusted in patients with baseline creatinine clearance <50 mL/min. Tenofovir should be used with caution in individuals with renal insufficiency or who are taking nephrotoxic medications. Fixed-dose combinations should not be used in patients who need dose adjustment due to renal failure.</p> <p>More about alternative nPEP regimens at http://nccc.ucsf.edu/wp-content/uploads/2014/04/CCC_PEP_Quick_Guide_Alternative_Regimen_and_Dosing_and_Toxicity_Tables.pdf</p>

PREGNANCY nPEP OPTIONS

If PEP is started for a pregnant exposed person, reasonable options include the following:

Tenofovir/emtricitabine (Truvada®, TDF/FTC) 1 tab daily + raltegravir (Isentress®, RAL) 400 mg BID	
<p>Pros</p> <ul style="list-style-type: none"> Well-tolerated TDF/FTC is a preferred agent in treating HIV+ pregnant women per DHHS guidelines RAL is an alternative agent in treating HIV+ pregnant women per DHHS guidelines Very low potential for drug-drug interactions 	<p>Cons</p> <ul style="list-style-type: none"> More limited experience using RAL in pregnancy vs. protease inhibitors (PIs)
OR	

Zidovudine/lamivudine (Combivir®, also available as generic, AZT/3TC) 1 tab BID + *lopinavir/ritonavir (Kaletra®, LPVr) 2-3 tablets BID	
Atazanavir (Reyataz) 300-400 mg daily + ritonavir 100 mg daily may be used in place of lopinavir/ritonavir. Pharmacokinetic data in pregnant women suggest increasing to 3 tabs BID of lopinavir/ritonavir and to 400 mg daily of atazanavir in the 2 nd and 3 rd trimesters.	
Pros <ul style="list-style-type: none"> • Extensive experience with use of AZT/3TC in pregnancy • Lopinavir/ritonavir as well as atazanavir/ritonavir are preferred agents in treating HIV+ pregnant women per DHHS guidelines 	Cons <ul style="list-style-type: none"> • More side effects: nausea, vomiting, diarrhea, headache, fatigue • AZT associated with hematologic toxicity • High drug-drug interaction potential with lopinavir/ritonavir or other PIs
Other PEP options may be considered in the event of intolerance, source patient with resistant virus, ARV access, or exposed person (EP) preference. In these instances, providers should seek expert consultation. The National HIV/AIDS Clinicians' Consultation Center is accessible at http://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide/ or by calling 1-888-448-4911.	

Modified and adapted from New York Department of Health AIDS Institute <http://www.hivguidelines.org/>

STD AND HEPATITIS TREATMENT/VACCINATION

Based upon the 2010 CDC Treatment Guidelines, assessment for STDs may be deferred per the option of the treatment provider and patient. Many specialists recommend preventative therapy at initial examination because follow up of patient can be difficult.

- STD Screening and Prevention Medication Regimen
 - An empiric antimicrobial regimen for chlamydia, gonorrhea, trichomonas and bacterial vaginosis
 - Ceftriaxone (250 mg IM in a single dose), **AND**
 - Metronidazole (2 g orally in a single dose), **AND**
 - Azithromycin (1 g orally in a single dose), **OR** Doxycycline (100 mg orally 2x a day for 7 days)
- **EMERGENCY CONTRACEPTION (EC)** should be offered if an exposure could result in pregnancy.

PREGNANCY TESTING

- All women of child-bearing potential should be tested for pregnancy.
- If the presenting exposure is vaginal, patient should return for repeat testing if her menstrual cycle is delayed.
- Pregnant women can receive nPEP but should not be given efavirenz or didanosine plus stavudine.
- For more information about antiretroviral use in pregnancy, refer to the *Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Perinatal HIV-1 Transmission in the US* at <http://www.cdc.gov/> or www.aidsinfo.nih.gov/guidelines/.

• HEPATITIS

- Post-exposure hepatitis B vaccination, without HBIG, should adequately protect against HBV infection.
- Hepatitis B vaccination should be administered to patients at the time of the initial examination if they have not been previously vaccinated.
- Follow-up doses of vaccine should be administered one to two and four to six months after the first dose.
- Hepatitis C testing optional.

PATIENTS WITH MULTIPLE EXPOSURES

Following a series of exposures, some individuals will present for nPEP both within and outside of the 72-hour nPEP treatment window. It is the decision of the health care provider to determine whether nPEP should or should not be offered in such circumstances. It is not unreasonable to offer nPEP, although there is reduced likelihood that nPEP will be able to prevent HIV infection due to earlier exposures.

STARTER PACK

A starter pack of the preferred regimen should be provided at the time of initial evaluation. A starter pack usually consists of a three- to five-day supply. NOTE: Medications can be changed at follow up if appropriate based on source patient resistance (if available), efficacy data, toxicity, pill burden/ease of dosing, potential drug interactions, cost and pregnancy risk. Prophylactic antiemetic and antidiarrheal agents can be used if necessary.

LENGTH OF THERAPY AND AMOUNT DISPENSED

The total nPEP treatment is 28 days and should NOT be administered for less than 28 days unless:

- The source is determined to be uninfected via confirmatory HIV test
- The exposed individual is determined to be HIV infected per confirmatory test
- There are intolerable side effects and no alternative medications are available

OR

- Exposed individual changes her/his mind about nPEP after re-examining the risks and benefits
- Individual health care providers should determine a schedule for dispensing nPEP
- If three or more days are missed consecutively, the patient should be advised to discontinue nPEP medication course

CONSENTS AND OTHER TESTING

If (1) the exposure occurred within the 72-hour time period, (2) the exposure is assessed as a risk by the health care provider and (3) the patient consents to 28 days of nPEP treatment, the following is needed:

- Consent for HIV testing and nPEP treatment
- Documentation of patient education regarding testing and treatment course of action
- Complete blood count (CBC)
- Serum liver enzymes
- Blood urea nitrogen (BUN)/creatinine
- Urinalysis

Modified from Plan of Action for Victims of Sexual Assault, State of Kentucky

PRACTITIONER CONSULTATION WITH A SPECIALIST IS RECOMMENDED

NOTE: If consultation is not immediately available, nPEP should not be delayed; changes can be made as needed after nPEP has been initiated. If the source is found to be HIV negative or nonreactive, nPEP should be discontinued. Delaying nPEP therapy in order to obtain resistance test results (genotyping or phenotyping) for the purpose of selecting more specific therapy is not advised. Exposed persons are frequently unable to complete nPEP regimens due to side effects. Providing prophylactic symptom management can improve adherence.

FOR PRACTITIONER CONSULTATION:

- NCCC nPEP Hotline: **1-888-448-4911**
- CDC HOTLINE: **1-800-232-4636**
- Southeast AIDS Education and Training Center
Vanderbilt Comprehensive Care Clinic: **(615) 875-7873**
Taryn Buckley, PhD, CHES or Linda James, MPS: **(352) 273-7845**
Martia West, MHP, Administrator: **(305) 582-2233**
<http://aidsetc.org/directory/regional/southeast-aids-education-and-training-center>

4 – REFERRAL, FOLLOW-UP AND MONITORING

All patients receiving nPEP should be re-evaluated within three days of the exposure to review the exposure and available source person data, evaluate adherence and monitor for side effects or toxicities associated with the nPEP regimen. The exposed person should be evaluated weekly while receiving nPEP to assess treatment adherence, side effects of treatment, interval physical complaints and emotional status.

Monitoring the exposed patient during nPEP treatment and the follow-up period should be provided by or in consultation with a clinician experienced in managing nPEP. Emergency departments, urgent care centers and other treating health centers should establish linkages with local HIV providers to facilitate easy referral of patients for follow-up care. Providers who do not have access to a clinician experienced in nPEP should use the HIV Clinician Consultation Center PEpline at 1-888-448-4911 for phone consultation. Hours of operation are: 9:00 a.m.–2:00 a.m. EST, seven days a week.

During the treatment period, other blood tests may be indicated to monitor for side effects of treatment. The timing and specific testing indicated varies based on the nPEP regimen used. See the table below from the CDC Guidelines. Clinicians should be aware of the resources available within the community that offer medical and supportive counseling/adherence services following non-occupational exposure. Patients with signs or symptoms of acute HIV infection should be referred for further assessment when nPEP is provided outside of an expert clinical context.

MONITORING RECOMMENDATIONS AFTER INITIATION OF nPEP REGIMENS FOLLOWING NON-OCCUPATIONAL EXPOSURES						
	Baseline	Week 1	Week 2	Week 3	Week 4	Week 12
Clinic Visit	√	√ Or by telephone	√ Or by telephone	√ Or by telephone	√	
Pregnancy Test	√					
Serum liver enzymes, BUN, creatinine, CBC ^a	√		√		√	
HIV Screening Test ^b	√				√	√
STI Screening (for exposures unrelated to sexual assault ^b)						
• GC/CT NAAT (based on site of exposure)						
• RPR (See HIV Prophylaxis for Victims of Sexual Assault for recommendations in cases of sexual assault.	√		√ (consider)			
Hepatitis B and C ^a	For post-exposure management for hepatitis B and C, see Section IX: Non-Occupational Exposures to Hepatitis B and C					
^a CBC should be obtained for all exposed persons at baseline. Follow-up CBC is indicated only for those receiving a zidovudine-containing regimen.						
^b Recommended even if nPEP is declined.						
Modified from New York State Department of Health AIDS Institute, 2000-2015. All Rights Reserved.						

HIV SEROLOGICAL SCREENING TESTS

A 4th generation HIV antigen/antibody combination test is the recommended serologic screening test. This test is an antibody/antigen combination immunoassay test which can simultaneously detect both HIV-1/HIV-2 antibodies and HIV-1 p24 antigens and will generally be positive within 14–15 days of infection. HIV screening should be confirmed with an FDA-approved HIV-1/HIV-2 antibody-differentiation assay. If the exposed person presents with signs or symptoms of acute HIV seroconversion, an HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay to diagnose acute HIV infection. A 4th generation HIV antigen/antibody combination test is the recommended serologic screening test (see the *CDC Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens* at <http://www.hivguidelines.org/wp-content/uploads/2014/10/cdc-testing-algorithm-10-10-2014.pdf>).

HIV SEROCONVERSION

If HIV infection develops after an exposure, it will generally occur within two to four weeks of exposure. HIV testing at baseline, 4 weeks, and 12 weeks is recommended after significant exposures, regardless of whether the individual accepts or declines PEP treatment. Point-of-care HIV tests (rapid tests) are less sensitive than laboratory-based HIV tests; therefore, exposed persons should be tested with laboratory-based HIV tests whenever possible.

Patients acutely infected with HIV will often experience at least some symptoms of the acute retroviral syndrome. Fever and flu-like symptoms are common in acute HIV infection but are nonspecific. Rash, mucocutaneous ulcers, oropharyngeal candidiasis and meningismus are more specific. Symptoms may also include fatigue or malaise, joint pain, headache, loss of appetite, night sweats, myalgias, lymphadenopathy, oral and/or genital ulcers, nausea, diarrhea or pharyngitis. Acute HIV infection is often not recognized in the primary care setting because of the similarity of the symptom complex with that of the flu or other common illnesses.

Modified from Plan of Action for Victims of Sexual Assault, State of Kentucky

REFERRALS

- Mental health/substance abuse may contribute significantly to the risk of subsequent exposures.
- nPEP should be provided with services that address ongoing needs of patient risk behaviors.
- Providers should be aware of local resources for mental health/substance abuse treatment.
- National Sexual Assault Telephone Hotline: Rape Crisis Center services to mitigate sexual assault trauma (1-800-656-HOPE).
- HIV Hotline for patients in need of HIV-specific support (1-800-CDC-INFO).
- Primary care referrals should also be available, when indicated.

For information about rape crisis services, see *HIV Prophylaxis for Victims of Sexual Assault*:

<http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-for-victims-of-sexual-assault/>

MAKING REFERRALS FOR nPEP FOLLOW UP

- Option 1: Each facility or clinic provider performing an examination, including sexual assault exams, should solicit a relationship with a qualified medical provider who is knowledgeable about HIV treatment and nPEP and has the ability to receive patients within three to five days of the initial exam and referral. The referred facility should be aware of the billing procedures and have the capacity for diagnostic laboratory testing (see sample billing/coding resource page in this document on page 29).
- Option 2: The initial facility's health care provider/physician may have the patient return to their facility for follow-up treatment if no other option is available.
- Option 3: If there is not an established relationship and/or no physician available, then sexual assault victims who have been assessed by a physician and have met the criteria for nPEP can be referred to another primary care provider or a local regional infectious disease physician.

PHARMACY CONSIDERATIONS

Pharmacists play a role in the dispensation of nPEP regimens. In order to ensure more timely access of nPEP medications to patients, providers should be aware that the use of "phone-in" oral prescriptions may result in faster dispensing and avoid situations where drug access might be limited. When nPEP is prescribed to a patient receiving other prescription and non-prescription medications, a complete drug profile review should take place to assess for any drug-drug interactions. No medications should be dispensed as part of an nPEP regimen if all medications are unavailable at the same time.

It is beneficial to coordinate with local pharmacies in determining which ones have nPEP medications in stock or can order them quickly. Providers can discuss the treatment with local pharmacies and the need for an urgent response when prescribing nPEP medications. Pharmacists with specific questions regarding nPEP therapy are welcome to contact the PEP Hotline at (888) 448-4911, available seven days a week from 9:00 a.m.–2:00 a.m. EST.

An HIV nPEP Discharge Instruction Form is provided on page 24 for use or modification.

Resources and Information for Non-Occupational Post Exposure Prophylaxis (nPEP)

Algorithm for Evaluation and Management for a Non-Occupational Exposure

STEP 1: Evaluation of exposure: Is nPEP indicated?

LOWER-RISK EXPOSURES:

- Oral-vaginal contact (receptive and insertive)
- Oral-anal contact (receptive and insertive)
- Receptive penile-oral contact with or without ejaculation
- Insertive penile-oral contact with or without ejaculation

STOP

nPEP not indicated. Provide risk-reduction counseling and offer HIV test.

HIGHER-RISK EXPOSURES:

- Receptive and insertive vaginal or anal intercourse with HIV+ or unknown source
- Needle sharing with HIV+ or unknown source
- Injuries with exposure to blood or other potentially infected fluids from HIV+ or unknown source (including needle sticks with a hollow-bore needle, human bites, accidents)

If nPEP is indicated, go to Step 2.

EXPOSURES THAT DO NOT WARRANT nPEP:

- Oral-to-oral contact without mucosal damage (kissing or mouth-to-mouth resuscitation)
- Human bites not involving blood
- Exposure to solid-bore needles or sharps not in recent contact with blood
- Mutual masturbation without skin breakdown or blood exposure

STOP

nPEP not indicated. Provide risk-reduction counseling and offer HIV test.

STEP 2: Is patient presenting within 72 hours?

CDC guidance is to initiate nPEP if patient presents within 72 hours of exposure.

See CDC MMWR 54(RR02); 1-20 January 21, 2005

YES

For further guidance, see <http://www.hivguidelines.org/>

STEP 3: TREATMENT - Initiate first dose of nPEP regimen—28 Day Regimen

tenofovir 300 mg PO qd + emtricitabine (TRUVADA®) 200 mg PO daily

PLUS

raltegravir (ISENRESS®) 400 mg PO bid

OR

dolutegravir (TIVICAY®) 50 mg PO daily

STEP 4: Baseline testing/labs

BASILINE TESTING OF EXPOSED PERSON:

- HIV test* (4th generation test preferred)
- GC/CT NAAT (based on site of exposure)
- RPR for syphilis
- Pregnancy test as appropriate
- Assess need for emergency contraception
- HBV and HCV: Check history for hepatitis B vaccines; if unknown, draw HBsAg
- Optional to screen for hepatitis C
- Complete Metabolic Profile (CMP)
- eGFR

nPEP should not be continued in those who decline baseline HIV testing.

See Section IX for hepatitis B and C post-exposure management, [Non-Occupational Exposures to Hepatitis B and C](#)



SOURCE TESTING, if source is available:

- Obtain consent for HIV testing
- Obtain HIV test as soon as possible with turnaround time <1 hour.
- If the test results are not immediately available, continue exposed person's nPEP while awaiting results.
- If the source person's HIV screening test result is negative, but there may have been exposure to HIV in the previous 6 weeks, obtain plasma HIV RNA assay.
- Continue exposed person's nPEP until results of the plasma HIV RNA assay are available.

WHEN THE SOURCE IS KNOWN TO BE HIV INFECTED:

Past and current ART experience, viral load data, and genotypic or phenotypic resistance data (if available) may indicate the use of an alternative nPEP regimen. Consult with a clinician experienced in managing nPEP.

STEP 5: Provide risk-reduction counseling

- Provide risk-reduction and primary prevention counseling.
- Refer for mental health and/or substance use programs when indicated; consider need for intensive risk-reduction counseling services.
- Discuss future use of Pre-exposure Prophylaxis (PrEP) with persons with ongoing risk behavior.

Modified and adapted from New York Department of Health AIDS Institute <http://www.hivguidelines.org/>

TRUVADA® INFORMATION SHEET

Drug Prescribed: **TRUVADA®** 200-300 MG TAB

Generic Name: EMTRICITABINE/TENOFOVIR TAB 200-300 MG



WARNING: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of the nucleoside analogs alone or in combination with other antiretrovirals. Please see additional information below.

WARNING: If you are infected with hepatitis B: Truvada® is NOT approved for the treatment of chronic hepatitis B Virus (HBV) infection and the safety and efficacy of Truvada® have not been established in patients co-infected with HBV. Severe acute exacerbations of HBV have been reported in patients who have discontinued the components of Truvada®. If there is risk of HBV infection, hepatic (liver) function should be monitored closely with both clinical and laboratory follow up.

WHY IS IT PRESCRIBED?

The reason you are being prescribed this medication today is for the prevention of HIV infection in combination with other antiretroviral agents. This medication is not a cure if you are already infected with HIV.

BEFORE USING THIS MEDICINE: Tell your doctor if you are PREGNANT or if you are having any of the following conditions: BONE DISEASE, LIVER PROBLEMS or KIDNEY DISEASE.

HOW MEDICINE IS ADMINISTERED?

Use this medicine exactly as directed on the label, unless instructed differently by your doctor.

- This medicine may be taken with or without food. Take at the same time each day.
- Patient should read specific "MEDICATION GUIDE" provided with this medicine before starting treatment and each time their prescription is renewed.
- A doctor should check you to make sure you don't have unwanted side effects.
- Do not decrease the dose or stop taking other prescribed medicines unless instructed by your physician or until you finish the 28-day course.

WHAT TO DO IF YOU MISS A DOSE?

Take when you remember unless it is time for the next dose. No double dose.

HOW THIS MEDICINE SHOULD BE STORED?

Keep in original closed container in a dark, cool and dry place away from children. Discard unneeded medicine.

WARNINGS/PRECAUTIONS:

- There is no adequate or well-controlled safety studies in pregnant women. Notify doctor if you are pregnant, if pregnancy is suspected or if you intend to become pregnant.
- It is not known if this drug is excreted in breast milk. Notify your doctor if you are breastfeeding.
- Notify doctor IMMEDIATELY of symptoms of LACTIC ACIDOSIS (malaise/extreme fatigue, muscle pain, respiratory distress, increased sleepiness and abdominal distress).
- LACTIC ACIDOSIS is a medical EMERGENCY that must be treated in a hospital setting. STOP taking the drug and seek emergency treatment immediately.
- Notify doctor of any signs suggesting LIVER problems (for example, unusual fatigue, loss of appetite, nausea, vomiting, yellowing of eyes, dark urine).
- DO NOT DRINK alcoholic beverages or take alcohol-containing preparations while being treated with this medicine.
- Because of INTERACTIONS, report the use of any other prescription or nonprescription medicines, including natural/herbal remedies, to your doctor.

ADVERSE REACTIONS:

Stop taking this medicine and get emergency help IMMEDIATELY if you experience:

Lactic acidosis or liver toxicity (yellow eyes or skin).

Stop taking this medicine and notify your doctor AS SOON AS POSSIBLE if you experience:

Burning pain, tingling or numbness; itching; skin rash; or severe skin itching with patches.

Other Common Side Effects:

High blood sugar level; anxiety; cough; fever; generalized pain; numbness or tingling in hands and feet; peripheral (arms/legs) nerve pain; headache; stomach discomfort or pain; back pain; muscle weakness; diarrhea; nausea; dizziness; darkening of skin; nasal congestion; decreased appetite; high triglycerides level; gas; vomiting; weight gain; depression; abnormal dreams; unusual tiredness or weakness; difficulty falling asleep; or abnormal laboratory studies, for example, creatinine and liver function tests.

If symptoms are mild but do not go away or are bothersome, check with your doctor. IF ANY OF THE ABOVE SIDE EFFECTS IS SEVERE, CALL YOUR DOCTOR IMMEDIATELY.

Call your doctor for medical advice about side effects.

This information has been developed by CliniDATA Source, Inc., based primarily on labeling information provided by the manufacturer. The information does not cover all possible uses, actions, precautions, side effect or interactions of this medicine. It is not intended as medical advice for individual patients.

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TIVICAY® INFORMATION SHEET

Drug Prescribed: **TIVICAY®** 50 MG TAB
Generic Name: DOLUTEGRAVIR TAB 50 MG



Tivicay® (dolutegravir) is a new antiretroviral agent to treat HIV-1 infection in treatment-naïve adults, and treatment-experienced adults (including those with prior integrase strand transfer inhibitor exposure); and treatment-naïve and treatment-experienced children ages 12 and older (weighing at least 40 kilograms), but who have never taken other integrase strand transfer inhibitors (INSTI-naïve).

Dolutegravir is an INSTI that binds to the HIV integrase active site blocking the strand transfer of HIV DNA integration, which is needed for HIV replication.

Clinical trials have shown dolutegravir-containing regimens to be effective in reducing viral loads. Common side effects included insomnia and headache. Serious side effects include hypersensitivity reactions and abnormal liver function in participants co-infected with hepatitis B and/or C. Advice on monitoring patients for serious side effects is included in the label.

Dose: The 50 mg tablet is to be taken once daily (without regard to meals) in combination with other antiretroviral drugs in adult patients, treatment-naïve or treatment-experienced, and INSTI-naïve.

INSTI-experienced adults with certain resistance mutations should be dosed at 50 mg twice daily. Clinical trial data revealed at 24 weeks showed baseline INSTI-associated mutations predicted response (VIKING-3 trial):

- 18% if Q148H/R + \geq 2 substitutions at L74I/M, E138A/D/K/T, G140A/S, Y143H/R, E157Q, G163E/K/Q/R/S, or G193E/R
- 80% if N155H without Q148
- 56% if Y143C/H/R present without Q148

Children \geq 12y/o and wt. \geq 40 kg and treatment-naïve or treatment-experienced, INSTI-naïve: 50 mg once daily.

ADVERSE EVENTS:

Headache and insomnia are the most common side effects. Also possible: hypersensitivity reaction, worsening transaminitis in those with underlying hepatitis B or C, fat redistribution, increased serum creatinine (due to inhibition of tubular secretion) without affecting renal glomerular filtration.

USE IN SPECIFIC POPULATIONS:

Pregnancy: Dolutegravir is labeled "Pregnancy Category B" and should be used during pregnancy only if clearly needed.

Hepatic Impairment: Dolutegravir is appropriate for treatment of patients with mild or moderate hepatic impairment, but is not recommended for use in patients with severe hepatic impairment (Child-Pugh Score C).

0

Renal Impairment: Dolutegravir is appropriate for treatment-naïve or treatment-experienced and INSTI-naïve patients with mild to severe renal impairment. Use with caution in INSTI-experienced patients with severe renal impairment, decreased dolutegravir concentrations could result in loss of therapeutic effect and development of resistance to dolutegravir or other co-administered antiretroviral agents.

DRUG INTERACTIONS:

Contraindications: Use of dolutegravir with dofetilide is contraindicated due to a risk of increased dofetilide plasma concentrations potentiating serious and/or life-threatening events. Dolutegravir inhibits the tubular secretion of creatinine without affecting renal glomerular function. Creatinine increase occurred within first 4 weeks (range -0.60 to 0.62 mg/dL; mean change from baseline 0.11 mg/dL) and remained stable through 48 weeks of the study.

If combined with efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir or rifampin, the dose should be increased to 50 mg twice daily. Dolutegravir 50 mg once daily can be combined with etravirine only if co-administered with atazanavir/ritonavir, or darunavir/ritonavir, or lopinavir/ritonavir. Do not combine with nevirapine; no data to make recommendation. Avoid co-administration with oxcarbazepine, phenytoin, phenobarbital, carbamazepine, and St. John's Wort, which are metabolic inducers, which decrease dolutegravir levels; no data to recommend dose adjustment. Metformin levels are increased by dolutegravir; monitor closely on starting or stopping dolutegravir.

<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=63df5af3-b8ac-4e76-9830-2dbb340af922>

ISENTRESS® INFORMATION SHEET

Drug Prescribed: **ISENTRESS®** 400 MG TAB
Generic Name: RALTEGRAVIR FILM COATED TAB 400 MG



WHY IS IT PRESCRIBED?

The reason you are being prescribed this medication today is for the prevention of HIV infection in combination with other antiretroviral agents. This medication is not a cure if you are already infected with HIV.

HOW MEDICINE IS ADMINISTERED?

Use this medicine exactly as directed on the label, unless instructed differently by your doctor.

WHAT TO DO IF YOU MISS A DOSE?

Take when you remember unless it is time for the next dose. No double dose.

HOW THIS MEDICINE SHOULD BE STORED?

Keep in original closed container in a dark, cool and dry place away from children. Discard unneeded medicine.

WARNINGS/PRECAUTIONS:

- Safety of use during pregnancy has not been established. This medicine **SHOULD NOT BE USED DURING PREGNANCY** unless benefit justifies potential risk to the fetus. **CALL YOUR DOCTOR.**
- Notify your doctor if you are a nursing mother before breast-feeding your baby.
- Notify your doctor if you are pregnant, if pregnancy is suspected or if you intend to become pregnant.

Common side effects:

Diarrhea, unusual tiredness or weakness, headache, hypersensitivity (allergic) reactions, nausea, muscle weakness, opportunistic infections.

If symptoms are mild but do not go away or are bothersome, check with your doctor. **IF ANY OF THE ABOVE SIDE EFFECTS IS SEVERE, CALL YOUR DOCTOR IMMEDIATELY.**

Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088.

This information has been developed by CliniDATA Source, Inc., based primarily on labeling information provided by the manufacturer. The information does not cover all possible uses, actions, precautions, side effects or interactions of this medicine. It is not intended as medical advice for individual patients.

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BILLING CODES FOR PEP & PREP

OCTOBER 1, 2015, is date set for ICD-10-CM/ICD-10-PCS Implementation: The U.S. Department of Health and Human Services (HHS) issued a rule that ICD-10-CM and ICD-10-PCS will be implemented into the HIPAA mandated code set on October 1, 2015. Click [HERE](#) for AAPC website and [HERE](#) for AMA info.

According to the American Association of Professional Coders (AAPC), the main differences between ICD-9-CM vs. ICD-10-CM are as follows: **ICD-9-CM** has only 13,600 codes, code composition is mostly numeric, with E and V codes alphanumeric, and valid codes have three, four, or five digits. Currently, ICD-9-CM codes are required and no mapping is necessary.

ICD-10-CM has 69,000 codes; composition codes are all alphanumeric, beginning with a letter and with a mix of numbers and letters thereafter; valid codes may have three, four, five, six or seven digits. For a period of two years or more, systems will need to access both ICD-9-CM codes and ICD-10-CM codes as the country transitions from ICD-9-CM to ICD-10-CM. Mapping will be necessary so that equivalent codes can be found for issues of disease tracking, medical necessity edits and outcomes studies.

COMMONLY USED BILLING CODES RELATED TO PEP & PREP

ICD-9	DESCRIPTION	ICD-10	DESCRIPTION	CPT	DESCRIPTION
V69.2	High-risk sexual behavior	Z72.5	High-risk sexual behavior	99401	Preventive counseling (15 minutes)
V01.79	Exposure to other viral diseases (including HIV)	Z20.82	Contact with and (suspected) exposure to other viral communicable diseases	99402	Preventive counseling (30 minutes)
				99403	Preventive counseling (45 minutes)
				99404	Preventive counseling (60 minutes)

ADDITIONAL PEP/PrEP-RELATED BILLING CODES

ICD-9	DESCRIPTION	ICD-10	DESCRIPTION	ICD-10	DESCRIPTION
V01	Contact with or exposure to communicable diseases	W46.0	Contact with hypodermic needle (hypodermic needle stick NOS)	B16.2	Acute hepatitis B without delta-agent with hepatic coma
V15.85	Exposure to potentially hazardous body fluid	W46.1	Contact with contaminated hypodermic needle	Z00.0	Encounter for general adult medical examination
E920.5	Needle stick	Z20.8	Contact with and (suspected) exposure to other communicable diseases	Z01.812	Encounter for preprocedural laboratory examination (blood and urine tests prior to treatment or procedure)
V01.8	Exposure to other communicable diseases	Z20.81	Contact with and (suspected) exposure to other bacterial communicable diseases	Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
V01.9	Contact with or exposure to unspecified communicable disease	Z20.9	Contact with and (suspected) exposure to unspecified communicable disease	Z11.4	Encounter for screening for human immunodeficiency virus (HIV)
V07.8	Other specified prophylactic measure	Z79	Long term (current) drug therapy. Includes long term (current) drug use for prophylactic purposes	Z11.59	Encounter for screening for other viral diseases
V58.83	Encounter for therapeutic drug monitoring	Z51.89	Encounter for other specified aftercare	Z11.8	Encounter for screening for other infectious and parasitic diseases
V07.9	Unspecified prophylactic measure	Z51.81	Therapeutic drug level monitoring	Z13.89	Encounter for screening for other disorder (encounter for screening for genitourinary disorders)
42	Human immunodeficiency virus illness or disease with symptoms	Z79.899	Other long term (current) drug therapy	Z13.9	Encounter for screening unspecified
V08	Human immunodeficiency virus infection, asymptomatic	B20	Human immunodeficiency virus (HIV) disease. Includes: AIDS; AIDS-related complex (ARC); HIV infection, symptomatic	Z32.0	Encounter for pregnancy test
70.3	Hepatitis, viral, type B (acute) without hepatic coma	Z21	Asymptomatic human immunodeficiency virus (HIV) infection status	Z70.0	Counseling related to sexual attitude
V02.61	Hepatitis, viral, type B carrier status	Z22.51	Carrier of viral hepatitis B	Z70.1	Counseling related to patient's sexual behavior and orientation
70.32	Hepatitis, viral, type B, chronic	B16.0	Acute hepatitis B with delta-agent with hepatic coma	Z70.3	Counseling related to sexual behavior and orientation of third party (child, partner, spouse)
70.31	Hepatitis, viral, type B, delta	B16.1	Acute hepatitis B with delta-agent without hepatic coma	Z72.51	High-risk heterosexual behavior
ICD-10	Description	B16.9	Acute hepatitis B without delta-agent and without hepatic coma	Z72.52	High-risk homosexual behavior
Z20	Contact with and (suspected) exposure to communicable diseases	B17.0	Acute delta-(super) infection of hepatitis B carrier	Z72.53	High-risk bisexual behavior
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	B18.0	Chronic viral hepatitis B with delta-agent		
Z20.5	Contact with and (suspected) exposure to viral hepatitis	B18.1	Chronic viral hepatitis B without delta-agent		
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus (HIV)				
Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids				
W46	Contact with hypodermic needle: "the appropriate 7th character is to be added to each code from category W46" A - initial encounter, D - subsequent encounter, S - sequela				

Adapted and modified from "PrEP Facts" brochure, San Francisco AIDS Foundation, Learn more at PrepFacts.org; American Association of Professional Coders (AAPC) at <https://www.aapc.com/>, and American Medical Assn (AMA) at <http://www.ama-assn.org/ama>

Non-Occupational Post-Exposure Prophylaxis (nPEP) Payment Options

MEDICAID	<ul style="list-style-type: none"> nPEP is covered (Florida Medicaid)
PRIVATE INSURANCE	<ul style="list-style-type: none"> nPEP coverage is determined by each plan; large co-pay(s) may be a consideration. Co-payment cards are available from the manufacturers. Gilead (Truvada®) - 1-877-505-6986 or http://www.gileadcopay.com/ Merck (Isentress®) - 1-855-834-3467 or https://www.activatecard.com/7119/# ViiV (Tivicay®) - 1-877-784-4842 or www.viivhealthcareforyou.com Patient Access Network Foundation (PAN), a non-profit organization, provides assistance to under-insured patients for their out-of-pocket expenses for HIV treatment and prevention, including PrEP or nPEP. Patient insurance must cover the medication for which the patient seeks assistance. Apply online by at https://www.panapply.org/ or call 1-866-316-PANF (7263). http://www.panfoundation.org/ Patient Advocate Foundation: http://www.patientadvocate.org/
UNINSURED & UNDERINSURED PATIENT ASSISTANCE PROGRAMS (PAP)	<ul style="list-style-type: none"> See specific application processes in this resource for Gilead, Merck, and ViiV patient assistance programs.
FOR SEXUAL ASSAULT VICTIMS	<ul style="list-style-type: none"> Funding sources may be available to pay for testing and treatment specifically for assault victims. For information about rape crisis services, see <i>HIV Prophylaxis for Victims of Sexual Assault</i>: http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-for-victims-of-sexual-assault/.

TRUVADA® (TENOFVIR + EMTRICITABINE) - nPEP PATIENT ASSISTANCE

OPTION # 1: Gilead's Advancing Access Program (1-800-226-2056)

(nPEP Recommended Dose: tenofovir/emtricitabine 300/200 mg (Truvada®) po daily x 28 days) and see Isentress® or Tivicay® options below).

Hours are Monday through Friday, 9:00 a.m.–8:00 p.m. EST.

1. Prepare a **Letter of Medical Necessity for nPEP** (see page sample letter in this resource) signed by a clinician, case manager, or victim advocate. Be sure to include patient's name, DOB, nPEP medication needed, date of exposure and signature of the clinician, case manager or victim advocate in the letter.
2. **Fax the Letter of Medical Necessity to 1-800-216-6857.** Make sure you indicate the **date and time of day** on the fax coversheet (this is how the fax will be located by the representative later). **A copy of prescription does not need to be faxed.**
3. Wait 20 minutes to be certain the fax has been received and processed. The clinician, case manager or victim advocate then calls **1-800-226-2056** and a representative will begin the prescreening process. The representative will ask for the date, time and number of pages faxed, and your fax number to locate the letter of necessity. Other information collected includes demographics, clinician name and possible health insurance. For the prescreening, have the **patient's household size and income available**. If no income, will need to provide how the patient is supported.
4. Patient will need to sign a consent form for Gilead's assistance. If patient is under 18 years of age, a parent or guardian will need to provide written consent.
5. If patient qualifies for the program, the representative will provide voucher, group number and BIN number. Patient takes this information to a retail pharmacy of their choice to receive a **30-day supply of Truvada® at no cost.** **NOTE:** If the exposure is greater than 72 hours, the client may not be approved for nPEP.

OPTION # 2: Patient Access Network Foundation (PAN):

If the patient has health insurance/Medicare/Medicaid, he or she may contact or be referred to the Patient Access Network Foundation (PAN) for assistance. Hours are Monday–Friday, 9:00 a.m. – 5:00 p.m. (EST). Phone: 866-316-7263. **NOTE: If the patient has Medicare Part D, he or she can only apply for PAN and not for the Co-Pay Program (below).**

Gilead's Co-Pay Coupon Program:

If the patient has commercial insurance, he or she may contact or be referred to Gilead's Co-Pay Coupon Program at 1-877-505-6986. Hours: Monday–Friday 8:00 a.m.–8:00 p.m. EST. The patient is given an authorization number to present with the prescription and other insurance at the pharmacy. For additional co-pay resources, please see <https://www.copays.org/>.

ISENRESS® (RALTEGRAVIR) - nPEP PATIENT ASSISTANCE

OPTION # 1: Merck's SUPPORT™ Program (1-800-350-3430)

(nPEP Recommended dose: raltegravir (Isentress®) 400 mg po twice a day x 28 days. See dolutegravir (Tivicay®) option below).

Hours are Monday through Friday, 9:00 a.m.–6:00 p.m. EST

Clinician may call **Merck's SUPPORT™ Program** prior to submitting the forms to alert the representative of the need for nPEP. The representative can then create a case number to hasten the approval process. Isentress® (raltegravir) *Patient Enrollment Form* (application) and instruction page located at http://merckhelps.com/docs/SUP_Enrollment_Form_English.pdf.

IMPORTANT: FILL OUT ALL SECTIONS OF APPLICATION COMPLETELY.

1. Patient must be a US resident and have a prescription for ISENTRESS® from a health care provider licensed in the United States.
2. Make sure all demographics and blanks are filled in; if applicant has no insurance, just write *NONE* in section 2.
3. Make sure to indicate where to ship medication (overnight shipping)—either patient's home or physician's office. If the enrollment is processed on the same day before 2:30 p.m. EST, it can be overnighted. If enrollment is not pulled, processed and approved BEFORE 2:30 p.m. EST, delivery may not be for 48 hours+, as delivery is not guaranteed and delivery times may differ depending on local shipper restrictions. If it is a Friday, consider shipping to patient's home; however, there is no guarantee it will be delivered on Saturday.
4. Patient signs/dates on pages 1 & 2; clinician fills out prescription in section 3, making sure to indicate quantity #60; clinician signs/dates section 4.
5. Write "**Prescribing PEP**" in the margins of BOTH pages of the application for quicker identification of urgency.
6. Fax to 1-866-410-1913.
7. Clinician/patient should call 1-800-350-3430 to confirm application has been received approximately 20–30 minutes after faxing the enrollment form.

OPTION # 2: Patient Access Network Foundation (PAN):

If the patient has health insurance/Medicare/Medicaid, he or she may contact or be referred to the Patient Access Network Foundation (PAN) for assistance. Hours are Monday–Friday, 9:00 a.m.–5:00 p.m. EST. Phone: 866-316-7263. For additional co-pay resources, please see <https://www.copays.org/>.

TIVICAY® (DOLUTEGRAVIR) - nPEP PATIENT ASSISTANCE

OPTION # 1: ViiV Patient Assistance Program (1-877-784-4842) Hours are Monday through Friday, 9:00 a.m.–7:00 p.m. EST.

For help completing the application, call ViiV Healthcare Patient Assistance Program at 1-877-7ViiVHC (1-877-784-4842) or go to www.viivhealthcareforyou.com/.

1) PHONE ENROLLMENT

- Provides a means for filling the prescription through a local pharmacy so patient can have quick access to the needed medication, but an **ADVOCATE** (someone involved in the delivery of the patient's health care, that is, a health care provider, social worker or case worker; NOT a family member or friend) must assist with the process.
- To become an **ADVOCATE**, call ViiV at 1-877-784-4842. As an **ADVOCATE**, you may enroll an nPEP Patient by phone in ViiV's Healthcare Patient Assistance Program (PAP) by phone and assist the nPEP patient to receive up to a 30-day supply of Tivicay® filled through a retail pharmacy.

2) ENROLLMENT APPLICATION BY THE ADVOCATE

- Application located at <http://www.viivhealthcareforyou.com/enrollment/enrollment-by-phone.html>. Print out, complete and sign the ViiV Healthcare Patient Assistance Program enrollment application.
- Gather income documentation, that is, the first page of Form-1040 tax form or paycheck stubs for the most recent 30 days. If retired, a copy of a Social Security letter may be used. If these documents are unavailable, the **ADVOCATE** may certify by signing/dating the "Advocate Certification" that applicant is acting in good faith as reporting accurate income.
- **ADVOCATE** will call 1-877-7ViiVHC (1-877-784-4842) for eligibility screening to determine if patient is eligible to receive medicine. The **ADVOCATE** faxes completed enrollment form and the proof of income.
 - a. **FOR MEDICARE PART D APPLICANTS:** The program requires the applicant to spend \$600 or more on prescription expenses since January 1st of present calendar year. The **ADVOCATE** and applicant submit a copy of Medicare Part D prescription drug plan card, pharmacy receipt(s) showing applicant paid at least \$600 for prescriptions in the current calendar year, the application and proof of income.
 - b. **IF THE PATIENT HAS MEDICARE PART D, BUT DOESN'T HAVE RECEIPTS:** Pharmacist may print/sign an itemized list of year-to-date patient medication to total at least \$600 if the patient did not keep receipts.
- **Patient goes to the pharmacy to have prescription filled and will need to take the following with them:**
 - a. ViiV Healthcare PAP **voucher** (provided by the **ADVOCATE** upon completion of enrollment by phone) **and**
 - b. The prescription for 30-day supply of Tivicay®.

OPTION # 2: Patient Access Network Foundation (PAN):

If the patient has health insurance/Medicare/Medicaid, he or she may contact or be referred to the Patient Access Network Foundation (PAN) for assistance. Their hours are Monday–Friday, 9:00 a.m.–5:00 p.m. EST. Phone: 866-316-7263.

For additional co-pay resources, please see <https://www.copays.org/>.

NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (nPEP) IN PEDIATRICS/ADOLESCENTS

There are currently no published guidelines for post-exposure prophylaxis from the CDC/PHS specific to the pediatric population. This guidance for pediatric post-exposure prophylaxis (PEP) regimens for known or possible exposures to HIV-infected body fluids can be used pending release of updated non-occupational exposure guidelines that will include pediatric dosing.

PEP REGIMEN OPTIONS: Standard occupational PEP regimens contain three drugs. There may be instances where two-drug PEP is acceptable. The decision to use two versus three drug PEP must take into consideration a variety of factors which may include, but are not limited to: the risk of the exposure, access to the drugs, cost, pill burden and tolerability. NOTE: AZT+3TC or TDF+FTC are options to two-drug PEP. For three-drug PEP, add either LPV/r or RAL.

References

- 1) Havens, P. & the Committee on Pediatric AIDS. Postexposure Prophylaxis in Children and Adolescents for Nonoccupational Exposure to Human Immunodeficiency Virus. American Academy of Pediatrics Clinical Report: Guidance for the Clinician in Rendering Pediatric Care. *Pediatrics*. 2003; 111(6): 1475-1489. Accessed at: <http://pediatrics.aappublications.org/content/111/6/1475.short?rss=1>
- 2) Centers for Disease Control and Prevention. Recommendations and Reports: Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States. Recommendations from the U.S. Department of Health and Human Services. *MMWR*. 2005. Accessed at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>
- 3) Kaufman, M. & the Committee on Adolescence. Care of the Adolescent Sexual Assault Victim. American Academy of Pediatrics Clinical Report. *Pediatrics*. 2008; 122: 462-470. Accessed at: <http://pediatrics.aappublications.org/content/122/2/462.full.pdf>
- 4) Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2010: Sexual Assault and STDs. Accessed at: <http://www.cdc.gov/std/treatment/2010/sexual-assault.htm>
- 5) New York State Department of Health AIDS Institute. HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period. Accessed at: <http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-post-exposure-prophylaxis-for-children-beyond-the-perinatal-period/>

Sample *Letter of Medical Necessity*
for use in obtaining Gilead's Truvada®

Date: _____

To Whom It May Concern,

This letter is written on behalf of patient, _____, DOB ____/____/____,
to support and confirm medically the necessity of treatment for post-exposure
prophylaxis.

This patient was exposed to the human immunodeficiency virus (HIV) on
_____ (date) at ____:____ (time) a.m. or p.m.

Please approve expeditiously the immediate coverage of emtricitabine/tenofovir
(Truvada®) so that the patient may begin treatment within the recommended 72-hour
timeframe of potential HIV exposure.

Sincerely,

Signature

<SIGNATURE BY CLINICIAN, CASE MANAGER, OR VICTIM ADVOCATE>

HIV nPEP DISCHARGE INSTRUCTIONS**Medical Record No:**
Name:

The following tests were conducted today:

- | | |
|---|---------------------------------------|
| <input type="checkbox"/> HIV test (rapid / 4 th gen / _____) | <input type="checkbox"/> GC/CT |
| <input type="checkbox"/> Pregnancy test | <input type="checkbox"/> Syphilis/RPR |
| <input type="checkbox"/> CMP | <input type="checkbox"/> eGFR |
| <input type="checkbox"/> Hepatitis B serology _____ | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Hepatitis C serology _____ | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> CBC | <input type="checkbox"/> Other _____ |

The following medications were prescribed today:**HIV Prophylaxis**

☐ You have been given a _____ day starter pack of medications. You will need to follow up with your primary care physician or an infectious disease physician in less than _____ days to receive counseling, blood tests and the remainder of the medication regimen to complete the 28-day dose.

Treatment for Gonorrhea

- ☐ Ceftriaxone (Rocephin) 250 mg IM in a single dose **PLUS**
☐ Azithromycin (Zithromax) 1 gram PO in a single dose

Treatment for Chlamydia

- ☐ Azithromycin (Zithromax) 1 gram PO in a single dose **OR**
☐ Doxycycline 100 mg PO twice a day for 7 days

Emergency Contraception

- ☐ Levonorgestrel (Plan B) 0.75 mg tablets: 1 tablet now and 1 tablet in 12 hours at _____

- ☐ Hepatitis B vaccination (Recombivax HB) 0.5 ml IM x 1 dose - **Series #1**

Series #2 due _____ (1 month)

Series #3 due _____ (6 months)

During my evaluation, it was determined that I may have been exposed to the HIV virus. I have consented to and been prescribed a 28-day nPEP medication regimen that may help prevent transmission of the HIV virus.

I understand that I need a follow up examination (with my clinic/doctor of choice), and I should bring this sheet so that my health care provider will know what treatment I received and can perform tests to be sure that the medications were effective.

I have been advised that during the 12-week follow-up period, I should:

- Use condoms to prevent sexual transmission
- Avoid pregnancy and breastfeeding
- Avoid needle-sharing
- Refrain from donating blood, plasma, organs, tissue or semen

I have been counseled on taking all of the medications as directed. I was counseled on the need to see a doctor/clinician within three (3) days of my exam. If I do not have a primary physician, I need to contact an infectious disease physician or other medical provider to schedule an appointment.

I will be certain to tell the medical facility with whom I am trying to get an appointment that I may have been exposed to HIV, that I have already started the nPEP medications, and that I need to see a physician within three (3) days of starting this medicine.

I will take a copy of this form along with my other discharge instructions to my medical provider.

Patient signature: _____**Date:** _____

Modified from Plan of Action for Victims of Sexual Assault, State of Kentucky

HIV NON-OCCUPATIONAL POST-EXPOSURE (nPEP) CHECKLIST

For further information see guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV available at: www.hivguidelines.org. This checklist is only intended as an aid and expert advice should be sought **before** use.

LAST NAME		FIRST NAME		
DATE	ID	DOB	SEX	ZIP CODE
Was the event a sexual assault? <input type="checkbox"/> Yes <input type="checkbox"/> No		If Yes, is the assailant known? <input type="checkbox"/> Yes <input type="checkbox"/> No		COMMENTS:
Date of Exposure / /		Time of Exposure : am/pm		
CHARACTERISTICS OF EXPOSURE				
Sexual contact		Drug Injection Exposure or Non-Sexual		
<input type="checkbox"/> Receptive anal sex: <input type="checkbox"/> ejaculation <input type="checkbox"/> withdrawal		<input type="checkbox"/> Reuse of injecting equipment <input type="checkbox"/> Other needlestick injury		
<input type="checkbox"/> Insertive anal sex: <input type="checkbox"/> circumcised <input type="checkbox"/> uncircumcised		<input type="checkbox"/> Other type		
<input type="checkbox"/> Receptive vaginal sex		<input type="checkbox"/> Superficial <input type="checkbox"/> non-intact skin <input type="checkbox"/> mucous membrane		
<input type="checkbox"/> Insertive vaginal sex: <input type="checkbox"/> circumcised <input type="checkbox"/> uncircumcised		<input type="checkbox"/> Under the influence of alcohol or drugs?		
<input type="checkbox"/> Receptive oral sex		Comments:		
<input type="checkbox"/> Insertive oral sex				
Other risks:				
Condoms used? <input type="checkbox"/> Yes <input type="checkbox"/> No				
Condom <input type="checkbox"/> broke <input type="checkbox"/> slipped <input type="checkbox"/> removed				
SOURCE - RISK CHARACTERISTICS				
Gender <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender				
HIV positive	Antiretroviral use	Source HIV risk	Partner	HBV
<input type="checkbox"/> known	<input type="checkbox"/> no ARV	<input type="checkbox"/> MSM	<input type="checkbox"/> regular	<input type="checkbox"/> +
<input type="checkbox"/> suspected	<input type="checkbox"/> unknown	<input type="checkbox"/> Injection drug use	<input type="checkbox"/> casual	<input type="checkbox"/> -
<input type="checkbox"/> unknown	<input type="checkbox"/> past ARV	<input type="checkbox"/> High prevalence area	<input type="checkbox"/> other	<input type="checkbox"/> known risk
<input type="checkbox"/> current ARV	HIV VL: <input type="checkbox"/>	<input type="checkbox"/> unknown	<input type="checkbox"/> partner unknown	
PATIENT - PREVIOUS TESTING				
Condition	Result	Date	Condition	Result
<input type="checkbox"/> HIV	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBcAb	<input type="checkbox"/> + <input type="checkbox"/> -
<input type="checkbox"/> Hepatitis C	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAg	<input type="checkbox"/> + <input type="checkbox"/> -
<input type="checkbox"/> Syphilis	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAb	<input type="checkbox"/> + <input type="checkbox"/> -
<input type="checkbox"/> Other STIs	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HepA immune	<input type="checkbox"/> + <input type="checkbox"/> -
PATIENT - BASELINE TESTING FOLLOWING CURRENT EXPOSURE				
Condition	Result	Date	Condition	Result
<input type="checkbox"/> HIV	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBcAb	<input type="checkbox"/> + <input type="checkbox"/> -
<input type="checkbox"/> Hepatitis C	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAg	<input type="checkbox"/> + <input type="checkbox"/> -
<input type="checkbox"/> Syphilis	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> HBsAb	<input type="checkbox"/> + <input type="checkbox"/> -
<input type="checkbox"/> GC/Chlamydia	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> Pregnancy	<input type="checkbox"/> + <input type="checkbox"/> -
<input type="checkbox"/> Other STIs	<input type="checkbox"/> + <input type="checkbox"/> -		<input type="checkbox"/> Blood Chemistry	<input type="checkbox"/> + <input type="checkbox"/> -
PATIENT - TRIAGE AND nPEP ASSESSMENT				
Date / /		Time : am/pm		Location:
Post-exposure prophylaxis for HIV recommended? <input type="checkbox"/> Yes <input type="checkbox"/> No		Hepatitis B vaccine / /		
nPEP Regimen started? <input type="checkbox"/> Yes <input type="checkbox"/> No		Was patient referred to counselling? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Has patient taken nPEP in the last 12 months? <input type="checkbox"/> Yes <input type="checkbox"/> No		If not, reason no referral was made:		
Did patient consent to receive nPEP? <input type="checkbox"/> Yes <input type="checkbox"/> No		Follow-up date / /		
Date nPEP was received / /		Time: : am/pm		
Follow-up location <input type="checkbox"/> PCP <input type="checkbox"/> CHD <input type="checkbox"/> CHC <input type="checkbox"/> Other				
Drugs prescribed	Dose	Frequency	I confirm that the above patient has had an exposure incident that may be a risk for HIV transmission. The result of the assessment for eligibility for HIV nPEP is documented and drugs prescribed.	
			Prescriber's Signature:	
			Prescriber's Printed Name:	
			Provider Number:	
Is emergency contraception indicated? <input type="checkbox"/> Yes <input type="checkbox"/> No		Contact Details:		
Was PrEP discussed? <input type="checkbox"/> Yes <input type="checkbox"/> No		Telephone:		

Modified and adapted from HIV nPEP form at: www.ashm.org.au/pep-guidelines

nPEP RESOURCES

CLINICIAN CONSULTATION CENTER (NCCC)

- For consultation on treatment of exposures to HIV (and HBV and HCV), clinicians managing exposed person(s) can call the Clinician Consultation Center - **Post-Exposure Prophylaxis Hotline (PEPline) at 888-448-4911. This service is available seven days a week from 9 a.m.–2 a.m. EST at no charge.** Additional information is available at the PEPline website, <http://www.nccc.ucsf.edu/>
- US Public Health Service *Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis*, 2013. http://nccc.ucsf.edu/wp-content/uploads/2014/03/Updated_USPHS_Guidelines_Mgmt_Occupational_Exposures_HIV_Recommendations_PEP.pdf
- *PEP HIV Basics* - <http://www.cdc.gov/hiv/basics/pep.html/>
- CDC *Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management*, <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm/>
- *Get Tested National HIV and STD Testing*. Put in your zip code and it searches for where areas with free testing. <https://gettested.cdc.gov/>
- US Public Health Service (USPHS) *Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*, 2001. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm/>; Appendix A: *USPHS Practice Recommendations for Health-Care Facilities Implementing the Guidelines for Management of Occupational Exposures to Bloodborne Pathogens*, 2001. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a2.htm>

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

- *Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States*. Source: CDC's Morbidity and Mortality Weekly Report, January 21, 2005/Vol. 54/No. RR-2;1-20; <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm>
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. Source: CDC's Morbidity and Mortality Weekly Report (MMWR), September 30, 2005/Vol.54/No. RR-9. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm>
- National Center for Emerging and Zoonotic Infectious Diseases (U.S.). Division of Healthcare Quality Promotion. Publish dated September 25, 2013. <http://stacks.cdc.gov/view/cdc/20711/>
- *Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis*. Recommendations for the management of health care providers who experience occupational exposure to blood and/or other body fluids that might contain HIV –dated September 2013. <http://www.ncbi.nlm.nih.gov/pubmed/23917901/>

Florida/Caribbean AIDS Education & Training Center (FCAETC.org)

- Pre-Exposure Prophylaxis (PrEP), Non-Occupational Post-Exposure Prophylaxis (nPEP) and Occupational PEP (oPEP). February 2015. <http://www.fcaetc.org/treatments/PrEPPEP.pdf>

AIDS.GOV

- Post-Exposure Prophylaxis at AIDS.gov. Information about post-exposure prophylaxis (PEP), including who should take PEP, when PEP should be started, where people can get PEP, and who pays for PEP. <http://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/>

ASHM.ORG.AU FAIR PRICING COALITION

- <http://www.ashm.org.au/pep-guidelines>
- Patient Assistance Programs and Co-Pay Programs for PEP. <http://fairpricingcoalition.org/patient-assistance-programs-and-co-pay-programs-for-pep/>

NASTAD

- *A Common Patient Assistance Program Application Form for HIV Medicine: Improved and Available*. <http://blog.nastad.org/2013/11/a-common-patient-assistance-program-application-form-for-hiv-medicine-improved-and-available/>

REFERENCES

nPEP

National Clinicians' Post-Exposure Prophylaxis Hotline (NCCC PEP Hotline)

For consultation on the treatment of exposures to HIV (and hepatitis B and C), the clinician managing the exposed person can call the National HIV/AIDS Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 888-HIV-4911. This service is available seven days a week from 9 a.m.–2 a.m. at no charge. Additional information is available at the PEPline website - <http://www.nccc.ucsf.edu/>

PEP - Centers for Disease Control and Prevention (CDC). Information about post-exposure prophylaxis (PEP), including who may benefit from receiving PEP, side effects of PEP and where and how people can get PEP - <http://www.cdc.gov/hiv/basics/pep.html>

Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States. Source: CDC's Morbidity and Mortality Weekly Report (MMWR), January 21, 2005/Vol. 54/No. RR-2 - <http://www.cdc.gov/mmwr/PDF/rr/rr5402.pdf>

Post-Exposure Prophylaxis at AIDS.gov
Information about post-exposure prophylaxis (PEP), including who should take PEP, when PEP should be started, where people can get PEP and who pays for PEP - <http://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/>

HIV Clinical Resource, Office of the Medical Director, New York State Department of Health AIDS Institute in collaboration with the Johns Hopkins University Division of Infectious Diseases. Updated October 2014
<http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/>

oPEP

Updated USPHS Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

Source: CDC - Authors: *USPHS Working Group on Occupational Postexposure Prophylaxis and National Center for Emerging and Zoonotic Infectious Diseases (U.S.). Division of Healthcare Quality Promotion.*
Publish date: September 25, 2013
<http://stacks.cdc.gov/view/cdc/20711>

Updated U.S. Public Health Service (USPHS) Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

Source: CDC's MMWR, September 30, 2005/Vol.54/No. RR-9 -
<http://www.cdc.gov/mmwr/PDF/rr/rr5409.pdf>
<http://www.jstor.org/stable/10.1086/672271>

Updated UPHS guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis - Recommendations for the management of health care providers who experience occupational exposure to blood and/or other body fluids that might contain HIV. Release date: September 2013 -
<http://www.ncbi.nlm.nih.gov/pubmed/23917901>

HIV Guidelines

Updates to the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents Updated: April 8, 2015 -
<http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0>

Updates to the Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents - What's New in the Guidelines Updated: April 16, 2015 -
<http://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/392/whats-new/>

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Some materials and guidance contained in this document have been modified or adapted from the following resources:

U.S. Public Health Services Guidelines, *Antiretroviral Post-exposure Prophylaxis After Sexual, Injection-Drug Use, or Other Non-Occupational Exposure to HIV in the United States*; DHHS, available at: <http://aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf>

Offering HIV Post-Exposure Prophylaxis (PEP) Following Non-Occupational Exposures Recommendations for Health Care Providers in the State of California; Office of AIDS, Department of Health Services.

<https://www.cdph.ca.gov/programs/aids/Documents/RPT2004OfferingPEPFollowingNonOccupExp2004-06.pdf>

Center for Disease Control and Prevention, *Sexually Transmitted Diseases Treatment Guidelines, 2015*; DHHS, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm>

Reprint of Executive Summary from *Offering HIV Post-Exposure Prophylaxis (PEP) Following Non-Occupational Exposures Recommendations for Health Care Providers in the State of California*; Office of AIDS, Department of Health Services. A full report may be obtained from <http://www.cdph.ca.gov/programs/aids/Pages/Default.aspx>

Havens, P.L., and the Committee on Pediatric AIDS. *Post-Exposure Prophylaxis in Children and Adolescents for Non-Occupational Exposure to Human Immunodeficiency Virus*. Pediatrics, 2003 June; 111(6): 1475-1489. <http://pediatrics.aappublications.org/content/111/6/1475>

Merchant, R.C. and Keshavarz, R. *Human Immunodeficiency Virus Post-Exposure Prophylaxis for Adolescents and Children*. Pediatrics, 2001 Aug; 108(2):E38 [68]. <http://www.ncbi.nlm.nih.gov/pubmed/11483848>

AAP 2015 Red Book: *Report of the Committee on Infectious Diseases*, 30th Edition, American Academy of Pediatrics. <http://shop.aap.org/Red-Book-2015-Report-of-the-Committee-on-Infectious-Diseases-30th-Edition-Paperback/>

Plan of Action for Victims of Sexual Assault, State of Kentucky, http://kbn.ky.gov/apply/Documents/nPEP_planofaction_FINAL_web_041111.pdf

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RESOURCES USED IN THE PREPARATION OF THIS DOCUMENT

- HIV Prophylaxis Following Non-Occupational Exposure, October 2014, New York State Department of Health AIDS Institute in collaboration with the Johns Hopkins University Division of Infectious Diseases, www.hivguidelines.org/
- Centers for Disease Control and Prevention (CDC) - Preventing New Infections, <http://www.cdc.gov/hiv/guidelines/preventing.html>
- Florida/Caribbean AIDS Education and Training Center <http://www.FCAETC.org>
- Plan of Action for Victims of Sexual Assault, State of Kentucky, http://kbn.ky.gov/apply/Documents/nPEP_planofaction_FINAL_web_041111.pdf
- “PrEP Facts,” San Francisco AIDS Foundation, www.PrePfacts.org
- American Association of Professional Coders (AAPC), <http://www.aapc.com>
- American Medical Assn (AMA), <http://www.ama-assn.org/ama>
- National Guidelines, from the Australasian Society for HIV Medicine (ASHM) www.ashm.org.au/pep-guidelines

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